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PART VI

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

■

ULTRASONIC THERAPY PRODUCTS

Radiation Safety Performance Standard

[4110-03]

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

[Docket No. 76N-0034]

PART 1050—PERFORMANCE STANDARDS FOR SONIC, INFRASONIC, AND ULTRASONIC RADIATION-EMITTING PRODUCTS

Ultrasonic Therapy Products

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This rule prescribes a radiation safety performance standard for ultrasonic therapy products for use in physical therapy. The standard applies to any device intended to generate and emit ultrasonic radiation for therapeutic purposes at frequencies above 16 kilohertz and to generators or applicators designed or specifically designated for use in such devices. The standard will require ultrasonic therapy equipment to be capable of delivering a prescribed amount of ultrasonic energy to the patient and will assure that sufficient information on beam characteristics is supplied to allow medical personnel to make informed judgments regarding the application of ultrasound energy.

EFFECTIVE DATE: February 17, 1979.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of June 14, 1976 (41 FR 23973), the Commissioner of Food and Drugs proposed to establish a radiation safety performance standard for ultrasonic therapy and surgery products because he recognized a need for a regulatory standard for such equipment to protect the public health and safety. Interested persons had until August 13, 1976, to file written comments on the proposal.

The agency received 13 comments on the proposal—six from government agencies (one foreign), three from health care organizations, two from manufacturers, one from a consumer, and one from a practitioner/user. Six comments generally supported the proposed standard; seven comments indicated neither approval nor disapproval, but suggested changes or additions to the regulation. A summary of the significant comments and the Commissioner's conclusions are as follows:

1. One comment asked that the standard require inspection of equipment currently in use.

Inspections of equipment would normally be part of the compliance program for an established performance standard. The Commissioner notes that the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90-602) does not authorize application of a performance standard to equipment manufactured before the effective date of the standard, and it would be inappropriate to include such a requirement. But he advises that manufacturers of currently marketed ultrasonic therapy products must have submitted detailed reports on their products to the Bureau of Radiological Health before the products were introduced into commerce. Also, some laboratory and field checks of equipment have been performed. Products manufactured after October 18, 1968, and found to have defects related to safety of use by reason of emission of electronic product radiation are subject to corrective action programs under the act, including the repurchase, repair, or replacement of such defective products.

2. A comment expressed concern that the standard would control the use of ultrasound therapy equipment and at the same time urged that the output power of such devices be correctly indicated to the user.

The Commissioner notes that the standard in no way places restrictions on the use of ultrasound therapy devices and that § 1050.10(c)(1) requires such devices to be equipped with a means to indicate the ultrasonic power within a specified precision. Therefore, no change in the standard is needed.

3. Two comments asked that information on coupling media and their effect on equipment performance be required under § 1050.10(f)(2).

The Commissioner believes that coupling media (fluid used between applicator and tissue to facilitate transmission of ultrasonic energy) have little effect on ultrasound attenuation or beam patterns; and, further, that there is little difference between different coupling media with regard to these parameters. Therefore, it is presently not justified to specifically require information on coupling media in the standard. However, the Commissioner emphasizes that if the radiation safety or dose delivery of a particular ultrasonic device were critically dependent on the choice of coupling medium, then the provisions of § 1050.10(f)(2)(i) would require such information to be supplied by the manufacturer.

4. One reviewer believed that the definition of "effective radiating surface" in § 1050.10(b)(11) is unnecessary because it is only used in the definition of "effective radiating area" in § 1050.10(b)(10). The comment also asserted that the reason for the 5 millimeter (mm) distance in § 1050.10(b)(11) is not clear. Because "effective radiating surface" is used in several definitions other than § 1050.10(b)(10), i.e., § 1050.10 (b)(1, (b)(7), and (b)(13), § 1050.10(b)(11) is considered appropriate. The choice of 5 mm distance from the applicator face as the distance at which to define "effective radiating surface" is consistent with the American Standard Specification for Ultrasonic Therapeutic Equipment of the American National Standards Institute (reference Z24.18-1956) and is considered reasonable. The Commissioner therefore rejects these comments.

5. A suggestion was made to change the definition of "focal length" in § 1050.10(b)(13) to avoid requiring measurements using a surface in space as a reference. The comment urged that the phrase "centroids of the effective radiating surface" be replaced with "center of the face of the transducer."

The Commissioner notes that the term "center of the face of the transducer" has no meaning for nonsymmetric surfaces and therefore is not accepting the revised definition. The current definition accounts for all possible transducer shapes.

6. One comment said that in § 1050.10(b)(19), in the definition of "pressure amplitude," the term $P_1(t)$ should be $p_1(t)$. The Commissioner agrees with the change and also is changing $P_2(t)$ to $p_2(t)$ in the definition.

7. One comment suggested that the international system of units (SI units) be used in the standard and that in particular, the SI unit for intensity, watts per square meter (Wm^{-2}), should be used rather than watts per square centimeter (Wcm^{-2}).

The Commissioner believes that while use of SI units would be desirable, it is necessary to deviate from that system in situations where a non-SI unit is commonly used in other related standards, common test instruments, and in manufacturing practice. Therefore, no changes are made. The Commissioner further notes that the unit Wcm^{-2} is consistent with SI units because a unit for intensity is not included in the international system of units. Although the SI unit for length is meters (m), it is acceptable to use a submultiple such as centimeters (cm).

8. One comment asked that the demarcation between modulated and continuous waveforms in § 1050.10(b)(7) be at a peak-to-average ratio of 1.25 rather than 1.05 so that the U.S. standard is compatible with that of the International Electrotechnical Commission (IEC).

The Commissioner is aware of evidence indicating that pulsed (modulat-

ed) ultrasound may be capable of producing biological effects other than thermal when compared to continuous-wave ultrasound of the same average intensity. A waveform characterized as continuous under the standard need not have any further information supplied with regard to temporal properties. For a waveform to be characterized as continuous it should have minimal amplitude variation with time, and the Commissioner concludes that the peak-to-average ratio of 1.05 should be retained. The Commissioner also notes that the value of 1.05 has been recommended by user groups while justification for the peak-to-average ratio in the IEC standard is not known to FDA. The Commissioner invites further data and information that would show that adopting the IEC provision would not adversely affect the public health.

9. One comment said the measurements of the beam cross-section as defined in § 1050.10(b)(3) and effective radiating area in § 1050.10(b)(10) seem to be impractical and should use the baffle technique in accordance with IEC Publication 150.

The baffle technique is a method where the beam area is determined by measuring the acoustic power passing through successively larger circular apertures and noting that aperture size for which 90 percent of the acoustic power is transmitted. The Commissioner advises that the baffle technique is impractical for the variety of transducer sizes and shapes currently available. There is general agreement within the U.S. delegation to the IEC that the scanning technique in this regulation is preferable to the baffle technique. The suggestion to change the measurement basis is therefore not accepted.

10. One comment suggested use of the IEC definition of "maximum intensity." Others asked that the terms "temporal-average," "temporal-maximum," "spatial-average," and "spatial-maximum" be defined.

The Commissioner disagrees that additional definitions are needed. The IEC definition of maximum intensity specifies measurements over a 1 centimeter diameter area, which is inappropriate for smaller transducers. The Commissioner does not believe the term "spatial-average" needs a definition because size of the detector used for determining spatial distribution of the ultrasonic field is specified in § 1050.10(e)(3). There is a generally accepted formal definition for "temporal-average" (IEEE Standard 100-1972 (Institute of Electrical and Electronics Engineers, Inc., 345 East 47th Street, New York, N.Y. 10017), ANSI C42.100-1972 (American National Standards Institute, Inc., 1430 Broadway, New York, N.Y. 10018)), which essentially defines the term as an average over one or more cycles of a periodic waveform. "Spatial-maximum" and "temporal-maximum" are self-explanatory in that they refer respectively to the greatest value over all space and the greatest value over all time.

11. One comment said there does not appear to be any important difference between the definitions of "focal area" and "focal surface" in § 1050.10 (b)(12) and (b)(14).

In accordance with strict mathematical usage, there is a difference between a surface and the area of a surface. Furthermore, the term "focal surface" is needed for the definition of "focal length" in § 1050.10(b)(13). The Commissioner believes that both definitions are needed, and therefore no change is made.

12. A suggestion was made that "ultrasonic frequency" as defined in § 1050.10(b)(23) should be expressed in megahertz (MHz) rather than Hertz (Hz) so that typical numbers used are kept small.

The Commissioner agrees with the suggestion and is changing the definition to allow the units of Hz, MHz, or kilohertz (kHz).

13. One comment stated that because the time average power for modulated waveforms is more important for patient treatment and safety than instantaneous power, the time average power should be used for calculating "ultrasonic power." Thus, the comment urged that § 1050.10(b)(24) require averaging emitted power over one cycle of the modulating waveform rather than over each cycle of the carrier wave. Another comment suggested that devices subject to §1050.10(c)(1)(ii) be required to indicate the temporal-average power and intensity as well as the temporal maximum power and intensity generated by the device because the average quantities are of as much importance in tissue heating as the maximum quantities.

As stated in paragraph 8 above, there is evidence that nonthermal biological effects associated with exposure to modulated ultrasonic radiation may be related to the temporal-maximum acoustic power and intensity of the waveform. Therefore, it is important that these quantities be indicated to the user. Users wanting to determine the time average power can do so by using the ratio of temporal-maximum to temporal-average effective intensity required by § 1050.10(d)(3)(ii) to be stated on the generator label. The Commissioner therefore concludes that no change in the standard is needed.

14. Two comments argued that the definition of an ultrasonic therapy product in § 1050.10(b)(25) should exclude devices with frequencies below 18 or 20 kHz because such devices produce audible radiation and are thus not "ultrasonic."

The Commissioner notes that there is no commonly accepted lower frequency limit for ultrasonic radiation. The lower frequency limit of 16 kHz will be retained in the standard to be consistent with possible future standards for other ultrasonic devices such as cleaners, rodent repellers, alarm systems, and dental devices, some of which operate below 20 kHz.

15. One comment said the 20-percent allowable error in proposed § 1050.10(c)(1)(ii) should apply individually to the errors in the power and intensity ratio rather than to the sum of the errors. In support of this, the comment noted that proposed § 1050.10(c)(1)(i) would permit a maximum error of ± 20 percent for the ultrasonic power of continuous waveforms.

The Commissioner does not accept the suggested change. The maximum allowable error of ±20 percent must be applied to the sum of the errors so that the temporal-average power may be derived from the two quantities with an error not exceeding ±20 percent. This would then be consistent with the maximum allowable error of ±20 percent for the temporal-average power in the case of continuous waveforms.

16. One comment stated that to label ultrasonic generators with the information required in § 1050.10(d)(3)(ii) would require too much space and that the data should only be required in accompanying documents. Similarly, except for frequency and maximum intensity information, the applicator label information required by §1050.10(d)(4)(iii) should only be required in the accompanying documents.

The Commissioner does not agree with the suggestion because such labeling information is necessary for each user of ultrasonic therapy products and this can only be assured if such information appears on the product. Accompanying documents may be misplaced by the user.

The Commissioner also advises that because ultrasonic therapy products are devices under the Federal Food, Drug, and Cosmetic Act, as amended, these products must also comply with the device labeling requirements in 21 CFR Part 801. To clarify this, special reference to Part 801 is added to § 1050.10(d). In cases where the labeling requirements of this regulation cannot be met because of space limitations, the Director of the Bureau of Radiological Health may approve alternate means of labeling (§ 1050.10(d)(5)).

17. One comment said the requirement in proposed §1050.10(e)(2)(iii) of ±10 percent for line voltage variations is too stringent for testing compliance with the error limits of § 1050.10(c)(1). It was noted that IEC Publication 150

allows additional ultrasonic power variations of ±10 percent for line voltage variations of ±5 percent.

The Commissioner believes that because line voltage variations of ±10 percent are not uncommon, the allowable error limits of ±20 percent in ultrasonic power indication should not be exceeded for such variations. Thus, a change in the regulation is not required, but the Commissioner welcomes further data and information that would show that less stringent provisions would not adversely affect the public health.

18. One comment suggested deletion of proposed § 1050.10(e)(3) because the specified detector size (i.e., with dimensions of less than one wave length in water) would often have dimensions of about 1 mm, an impractical size.

The Commissioner rejects the suggestion because detectors with dimensions as small as 0.25 mm are commercially available. This corresponds to an ultrasonic frequency of about 6 MHz. Furthermore, no marketed ultrasonic therapy products now operate above about 1 MHz, which would require a detector size no larger than about 1.5 mm. It is unlikely that products operating above 3 MHz (corresponding to a detector size of approximately 0.75 mm) will be marketed because the attenuation would be too great. It should also be noted that § 1050.10(e)(3) allows for an "equivalent measurement technique" in cases where compliance with the detector size requirement would be impractical.

19. One comment urged that instead of only requiring that the user be informed of the percentage errors in frequency and effective radiating area (§ 1050.10(f)(2)(iii)), maximum allowable errors for these parameters should be specified in § 1050.10(c). The comment noted that the IEC error limits for frequency and effective radiating area are ±5 percent and ±10 percent, respectively.

The Commissioner has insufficient information to justify specific error limits for ultrasonic frequency and effective radiating area. However, for an ultrasonic therapy product to be used properly, the errors in these parameters must be known by the practitioner. The Commissioner believes this will be effectively done via the user information required by § 1050.10(f)(2)(iii). He also advises that the quantities derived from the effective radiating area, such as the temporal-average effective intensity, are subject to error limits in § 1050.10(c)(1). The Commissioner welcomes data and information that would show the need for also specifying frequency and effective radiating area error limits.

20. One comment asked that the standard require manufacturers to supply maintenance manuals containing considerable explanatory information so hospital personnel can provide proper preventive maintenance on the devices. The comment also said FDA should monitor this required information to assure that the testing methods and maintenance scheduling are essential and necessary.

The Commissioner advises that § 1050.10(f)(1) already requires manufacturers to provide a maintenance schedule and instructions for operation, service, and calibration necessary to keep equipment in compliance with the standard. In addition, through its compliance programs, FDA will monitor the required informational material to assure that it is adequate.

21. One comment asked if the tests for compliance with the standard are intended for hospitals using the devices. If so, some of the required measurements, such as for the effective radiating area, would entail a sophisticated measuring capability and might have a significant cost impact.

The Commissioner points out that the compliance tests in § 1050.10(e) are not intended to be routine maintenance procedures. These are tests upon which manufacturers base their certification that a device is in compliance with the standard and which provide the basis for compliance measurements made by FDA. The device must remain in compliance with the standard for its useful life, provided the manufacturer's instructions for operation, service, and calibration are followed.

22. One comment said the large discrepancy between indicated and measured output from ultrasonic therapy products demonstrates the need for a performance standard. However, while admitting that such devices can induce damage to cells and tissues, the respondent alleged there is no evidence that the devices create a health hazard.

The need and rationale for this standard is discussed at length in the preamble to the June 14, 1976 proposal. The Commissioner notes that there have been documented instances of serious patient injury from exposure to ultrasound therapy (Medical World News, September 1964; Journal of the American Podiatry Association, Vol. 50, No. 8, p. 650; ibid, Vol. 51, No. 8, p. 574, copies of which are on file with the Hearing Clerk, FDA). As the comment notes, the need for a standard is justified on the basis of discrepancies between indicated and actual operating parameters. The potential for human injury and the known biological effects of ultrasound are sufficient reasons for development of a performance standard, even if documented cases of patient injury were not available.

23. One comment contained the suggestion that the standard should include a temperature limitation for the transducer face.

The Commissioner is not aware of any evidence that heating of the transducer face has produced actual problems in the use of ultrasonic therapy products. This lack of such evidence, along with the expected problems of technical feasibility of temperature measurements on the transducer face, has led to the rejection of such a requirement at the present time.

24. One comment recommended that a tolerance (e.g., ±5° C) be included with the specified temperature (30° C) of the measurement medium in § 1050.10(e)(2)(ii).

The Commissioner notes that water temperature is not a critical factor for the required measurements. A temperature is specified simply to standardize the procedures. It would be difficult to justify a temperature tolerance limit on the basis of protection of the public health and safety, and the Commissioner advises that he did not intend the stated temperature to represent an exact number. Furthermore, the regulation describes an idealized situation and only requires that an equivalent measurement medium be used. For example, oil at 20° C could be used instead of water at 30° C, provided the measurements were corrected to the idealized situation described in § 1050.10(e)(2)(ii). If it proves necessary, the Bureau of Radiological Health will provide a compliance guide for this standard, describing acceptable measurement techniques.

25. One comment on proposed § 1050.10(f)(2)(ii) said the user information should include at least one measurement of the ultrasonic radiation field along the applicator axis. The comment also said that a more rigorous specification of the number and accuracy of the required measurements should be included.

The Commissioner rejects the suggestions because the types of measurements necessary for an adequate description of the ultrasound field depend on the applicator configuration and thus vary.

26. One comment asked about the purpose of the visual indicator required in § 1050.10(c)(5). The comment said that a nonquantitative indication of electrical energy input to the transducer is not sufficient and that a quantitative indication of acoustic output from the applicator should be required.

The Commissioner advises that the visual indicator in § 1050.10(c)(5) is intended merely to alert the operator that the ultrasonic transducer(s) is energized. Quantitative indications of the power and intensity are required by § 1050.10(c)(1). It should be noted that the means necessary to comply with § 1050.10(c)(1) could be so de-

signed as to also fulfill the requirements of § 1050.10(c)(5).

27. One comment recommended that the standard require that a booklet of condensed operating instructions be affixed to the device.

The Commissioner believes that such a requirement is inappropriate and unnecessary. Manufacturers are required by § 1050.10(f)(2) to supply adequate operating instructions. It would not be prudent to have incomplete instructions affixed to the devices. Furthermore, the likelihood of persons losing or not using the currently required instructions for this type of medical device should be much less than for consumer products such as microwave ovens.

28. One comment questioned the need for the labeling information in § 1050.10(d)(3) concerning the ratio of temporal-maximum effective intensity to the temporal-average effective intensity (peak-to-average ratio). The comment said that most clinical situations do not require determining the relation between peak and average outputs.

The Commissioner believes that the labeling information should not be changed because the peak-to-average ratio is necessary to be able to convert from peak intensity to average intensity when operating in the pulsed mode. The average intensity must be known to be able to determine the tissue-heating effect (see paragraph 13, above).

29. One comment recommended that the description of the ultrasonic radiation field required in § 1050.10(f)(2)(ii) be provided for each applicator rather than for a model line because there can be vast differences between individual applicators of the same model.

The Commissioner has determined that no change is needed in the regulation. As currently worded, the description of the ultrasonic radiation field spatial distribution must be for the specific device with which the applicator is supplied. If there were significant differences between devices of the same model, individualized information would be necessary to comply with § 1050.10(f)(2)(ii).

30. One comment said the proposed warning in § 1050.10(f)(2)(iv) against adjusting nonuser controls is inadequate and misleading. The comment argued that by this warning, the manufacturer is granted exclusive responsibility and authority for nonoperator device adjustment, even though the user, such as a hospital, has qualified resident service personnel.

The intent of the warning is to caution untrained individuals that service controls or adjustments should not be used during normal operation. The Commissioner realizes that not all expertise rests with the manufacturer and advises that he did not intend to grant exclusive authority to perform service to any group. In fact, § 1050.10(f)(1), which requires that servicing information be provided to any person, is intended to make appropriate instructions available to all service personnel, including qualified hospital service personnel.

31. One comment noted that the "periodic" functions mentioned in § 1050.10(b)(19) are actually "quasi-periodic" because they are periodic functions multiplied by two step functions. The comment acknowleged that the distinction is unimportant for ultrasonic products for use in physical therapy, but suggested it may in the future be important for ultrasonic surgery products.

The Commissioner believes that no changes are needed in the regulation because the distinction between periodic and quasi-periodic waveforms for the equipment covered by this standard does not affect safety and health considerations. The need to distinguish between the functions will be considered for any future regulation applicable to ultrasonic surgery products.

32. A comment said the requirement for servicing information in § 1050.10(f)(1) is too vague and suggested that the following technical information should be specifically required: circuit diagrams, parts list, repair and service check lists, recommended preventive maintenance program and schedule, operational tests, block diagram if applicable, and installation manual. The comment also urged that consumer service personnel be specifically identified as persons to whom servicing information is to be made available by manufacturers.

The Commissioner does not agree. The regulation currently requires that adequate instructions be provided specifically including several items similar to those mentioned by the comment, e.g., maintenance schedule and calibration information. If information described in the comment is considered necessary for radiation safety reasons, such information must be provided by the manufacturer to meet the intent of § 1050.10(f)(1). However, the necessary information may vary from product to product, and so it is not practical to exactly specify a complete list of required information. Finally, § 1050.10(f)(1) currently requires that servicing information be made available to all persons upon request.

33. One manufacturer of ultrasonic therapy devices believes that the allowable tolerances for the timer in § 1050.10(c)(2) are too restrictive. The information accompanying the comment describes a 15-minute and 30-minute timer, though only the former is employed in ultrasonic therapy devices known to FDA. The 15-minute timer would not comply with § 1050.10(c)(2) for times less than 7.5 minutes, where its accuracy would be ±45 seconds (the standard requires ±0.5 minute for times less than 5 minutes, ±10 percent for times from 5 to 10 minutes, and ±1 minute for emission times greater than 10 minutes).

The Commissioner believes that the timer accuracy specifications in the proposal are necessary to assure that neither significant overexposures or underexposures occur for short treatment times (less than 7.5 minutes). It should be noted that underexposure may result in unnecessary exposure because the therapeutic effect may not occur with less than the prescribed exposure. The agency understands that short exposure times are being used in fractionated treatment regimens. Furthermore, the accuracy requirements could economically be met by currently available and relatively inexpensive timers.

34. One comment said the ratio of smallest beam cross-section to effective radiating area in the definition of focusing applicator (§ 1050.10(b)(15)) should be 0.95 rather than 0.5, to be consistent with the value of 1.05 for the peak-to-average pressure amplitude ratio in § 1050.10(b)(7). It suggested alternatively that the peak-to-average ratio be taken as 1.25 and the cross section-to-radiating area ratio be taken as 0.75. Those values would be consistent with IEC terminology (see comment 8, above).

The Commissioner does not accept the suggestion because there is no apparent reason why the demarcation between continuous and modulated waveforms should be at the same level as the demarcation between focusing and nonfocusing applicators. The spatial distribution of the ultrasonic field must be provided for all (focusing and nonfocusing) applicators. However, indication of temporal characteristics is required only for modulated waveforms. Therefore, waveforms characterized as continuous must have minimal temporal variations, i.e., peak-to-average amplitude ratio less than or equal to 1.05. However, as also stated in response to comment 8 above, the Commissioner welcomes further data and information that would justify adopting IEC provisions.

35. One manufacturer said the requirement for unique identification of applicators in § 1050.10(d)(4) implies a variability between applicators. Provision should be made for permanently attached applicators and for field replacement where all available applicators are essentially identical. To provide for this, the comment suggested that the phrase "Unless the applicator is permanently attached, or unless all physically interchangeable applicators are identical insofar as the parameters defined in (iii) below are concerned,

* * *" be inserted at the beginning of the introductory sentence of § 1050.10(d)(4).

The Commissioner is not changing the requirement because it is important to have all applicators individually labeled for those situations where different applicators do vary significantly. From a practical standpoint, because applicators are subject to specific performance requirements of this regulation and to the certification requirements of § 1010.2 (21 CFR 1010.2), the labeling in § 1050.10(d)(4) would be important for recall purposes in cases of noncompliance. Further, the Commissioner believes it would be difficult to adequately define the term "permanently attached." Most currently available applicators would probably be considered detachable.

36. One comment said a maintenance schedule as required by § 1050.10 (f)(1) and (f)(2)(i) is not always necessary and should be included in instructions only where necessary.

The Commissioner believes that no change in the regulation is needed. As currently worded, § 1050.10 (f)(1) and (f)(2)(i) refer to "a schedule of maintenance necessary to keep equipment in compliance." Thus instructions for service and for users would not require a maintenance schedule provided the manufacturer could substantiate that no maintenance is necessary to keep the device in compliance with the standard.

37. A manufacturer said the warning in § 1050.10(f)(2)(iv) is undesirable because: (1) Air is a poor conductor of ultrasound so the only danger is through direct contact with the transducer; (2) periosteal pain is a far more sensitive warning than any document; (3) such a warning detracts from the more significant warnings of electric shock, fire, and burn hazards, which are required by FDA and Underwriters Laboratory; (4) the warning is easily misunderstood by laymen, requiring extensive explanation that the "hazardous radiation" does not refer to ionizing radiation (e.g., x-rays) or ultraviolet radiation.

The Commissioner agrees that the term "hazardous radiation" could be misleading and is changing the warning to clarify that the attendant hazards derive from ultrasonic energy. However, he remains convinced the warning is necessary to divert nonservice personnel from changing nonuser controls or adjustments that might result in incorrect patient dose application and/or unintended exposure to the patient or operator.

38. One comment suggested that the applicator label required in § 1050.10(d)(4) should include the serial number(s) of designated generators to clarify to which generators the applicator has been tuned.

The Commissioner believes that requiring a specific generator serial number on an applicator implies that it should only be used with that specific generator even though with proper tuning and recalibration most applicators are interchangeable. He therefore rejects the suggestion.

39. One reviewer recommended that the user information required in § 1050.10(f)(2)(i) include a description of any known procedures that could alter compliance of the product with the standard.

The Commissioner is not changing the regulation because § 1050.10(f)(2)(i) already requires instructions on safe use, safety procedures, and precautions that may be necessary regarding the use of ultrasonic radiation. Also, § 1050.10(f)(2)(iv) requires a warning against possibly hazardous adjustments or procedures.

On his own initiative the Commissioner is changing the wording of § 1050.10(a) on applicability and § 1050.10(b)(25) defining "ultrasonic therapy product," to better reflect the original intent of this standard. The standard is intended to apply to ultrasonic devices used in physical therapy primarily for deep tissue heating. All currently known ultrasonic surgery devices (including those for cataract removal) operate by a mechanical vibratory action and have significantly different characteristics from devices used in physical therapy and so are not included in this regulation. The proposed standard excluded "products designed for use in dentistry," although the intent was to exclude only dental scaling devices. A specific exclusion of ultrasonic dental scalers is not needed because such devices are not used in physical therapy. Ultrasonic devices not covered by this regulation may be the subject of future FDA regulatory action.

The Physical Medicine Device Classification Panel and the American Academy of Physical Medicine and Rehabilitation expressed concerns that requirements be developed to assure that ultrasonic therapy devices provide sufficient power output to achieve therapeutic effectiveness. The commissioner welcomes further comments, suggestions, and supporting information on the need for such requirements. Such requirements, including appropriate indications for use and any necessary restrictions on use, will be considered at a later date in accordance with the priorities and other recommendations made by the appropriate classification panel.

Therefore, under the Public Health Service Act as amended by the Radiation Control for Health and Safety Act of 1968 (sec. 358, 82 Stat. 1177-1179 (42 U.S.C. 263f)) and under authority delegated to him (21 CFR 5.1), the Commissioner amends Chapter I, Subchapter J of Title 21 of the Code of Federal Regulations by adding new Part 1050, to read as follows:

§ 1050.10 Ultrasonic therapy products.

(a) *Applicability.* The provisions of this section are applicable as specified herein to any ultrasonic therapy product for use in physical therapy manufactured on or after February 17, 1979.

(b) *Definitions.* The following definitions apply to words and phrases used in this section:

(1) "Amplitude modulated waveform" means a waveform in which the ratio of the temporal-maximum pressure amplitude spatially averaged over the effective radiating surface to the root-mean-square pressure amplitude spatially averaged over the effective radiating surface is greater than 1.05.

(2) "Applicator" means that portion of a fully assembled ultrasonic therapy product that is designed to emit ultrasonic radiation and which includes one or more ultrasonic transducers and any associated housing.

(3) "Beam cross-section" means the surface in any plane consisting of the points at which the intensity is greater than 5 percent of the spatial-maximum intensity in that plane.

(4) "Beam nonuniformity ratio" means the ratio of the temporal-average spatial-maximum intensity to the temporal-average effective intensity.

(5) "Centroid of a surface" means the point whose coordinates are the mean values of the coordinates of the points of the surface.

(6) "Collimating applicator" means an applicator that does not meet the definition of a focusing applicator as specified in paragraph (b)(15) of this section and for which the ratio of the area of at least one beam cross-section, whose centroid is 12 centimeters from the centroid of the effective radiating surface, to the area of the effective radiating surface is less than two.

(7) "Continuous-wave waveform" means a waveform in which the ratio of the temporal-maximum pressure amplitude spatially averaged over the effective radiating surface to the root-mean-square pressure amplitude spatially averaged over the effective radiating surface is less than or equal to 1.05.

(8) "Diverging applicator" means an applicator that does not meet the definition of a collimating applicator or a focusing applicator as specified in paragraphs (b) (6) and (15) of this section.

(9) "Effective intensity" means the ratio of the ultrasonic power to the focal area for a focusing applicator. For all other applicators, the effective intensity is the ratio of the ultrasonic power to the effective radiating area. Effective intensity is expressed in watts per square centimeter (Wcm^{-2}).

(10) "Effective radiating area" means the area consisting of all points

of the effective radiating surface at which the intensity is 5 percent or more of the maximum intensity at the effective radiating surface, expressed in square centimeters (cm^2).

(11) "Effective radiating surface" means the surface consisting of all points 5 millimeters from the applicator face.

(12) "Focal area" means the area of the focal surface, expressed in square centimeters (cm^2).

(13) "Focal length" means the distance between the centroids of the effective radiating surface and the focal surface, for a focusing applicator, expressed in centimeters (cm).

(14) "Focal surface" means the beam cross-section with the smallest area of a focusing applicator.

(15) "Focusing applicator" means an applicator in which the ratio of the area of the beam cross-section with the smallest area to the effective radiating area is less than one-half.

(16) "Generator" means that portion of a fully assembled ultrasonic therapy product that supplies electrical energy to the applicator. The generator may include, but is not limited to, a power supply, ultrasonic frequency oscillator, service controls, operation controls, and a cabinet to house these components.

(17) "Maximum beam nonuniformity ratio" means the maximum value of the beam nonuniformity ratio characteristic of a model of an ultrasonic therapy product.

(18) "Operation control" means any control used during operation of an ultrasonic therapy product that affects the ultrasonic radiation emitted by the applicator.

(19) "Pressure amplitude" means the instantaneous value of the modulating waveform, and is $p_1(t)$ in the expression for a pressure wave, $p(t)=p_1(t)\,p_2(t)$, where $p(t)$ is the instantaneous pressure, $p_1(t)$ is the modulating envelope, and $p_2(t)$ is the relative amplitude of the carrier wave normalized to a peak height of one. All are periodic functions of time, t, at any point in space. The period of $p_1(t)$ is greater than the period of $p_2(t)$.

(20) "Pulse duration" means a time interval, expressed in seconds, beginning at the first time the pressure amplitude exceeds the minimum pressure amplitude plus 10 percent of the difference between the maximum and minimum pressure amplitudes, and ending at the last time the pressure amplitude returns to this value.

(21) "Pulse repetition rate" means the repetition frequency of the waveform modulating the ultrasonic carrier wave expressed in pulses per second (pps).

(22) "Service control" means any control provided for the purpose of adjustment that is not used during operation and can affect the ultrasonic radiation emitted by the applicator, or can alter the calibration or accuracy of an indicator or operation control.

(23) "Ultrasonic frequency" means the frequency of the ultrasonic radiation carrier wave, expressed in Hertz (Hz), kilohertz (kHz), or megahertz (MHz).

(24) "Ultrasonic power" means the total power emitted in the form of ultrasonic radiation by the applicator averaged over each cycle of the ultrasonic radiation carrier wave, expressed in watts.

(25) "Ultrasonic therapy product" means:

(i) Any device intended to generate and emit ultrasonic radiation for therapeutic purposes at ultrasonic frequencies above 16 kilohertz (kHz); or

(ii) Any generator or applicator designed or specifically designated for use in a device as specified in paragraph (b)(25)(i) of this section.

(26) "Ultrasonic transducer" means a device used to convert electrical energy of ultrasonic frequency into ultrasonic radiation or vice versa.

(c) *Performance requirements.* The requirements of this paragraph are applicable to each ultrasonic therapy product as defined in paragraph (b)(25) of this section when the generator and applicator are designated or intended for use together, or to each generator when the applicator(s) intended for use with the generator does not contain controls that affect the functioning of the generator.

(1) *Ultrasonic power and intensity—*(i) *Continuous-wave waveform operation.* A means shall be incorporated to indicate the magnitudes of the temporal-average ultrasonic power and the temporal-average effective intensity when emission is of continuous-wave waveform. The error in the indication of the temporal-average ultrasonic power shall not exceed ±20 percent for all emissions greater than 10 percent of the maximum emission.

(ii) *Amplitude-modulated waveform operation.* A means shall be incorporated to indicate the magnitudes of the temporal-maximum ultrasonic power and the temporal-maximum effective intensity when the emission is of amplitude-modulated waveform. The sum of the errors in the indications of the temporal-maximum ultrasonic power and the ratio of the temporal-maximum effective intensity to the temporal-average effective intensity specified in paragraph (d)(3)(ii) of this section shall not exceed ±20 percent for all emissions greater than 10 percent of the maximum emission.

(2) *Treatment time.* A means shall be incorporated to enable the duration of emission of ultrasonic radiation for treatment to be preset and such means shall terminate emission at the end of the preset time. Means shall also be incorporated to enable termination of emission at any time. Means shall be incorporated to indicate the magnitude of the duration of emission (expressed in minutes) to within 0.5 minute of the preset duration of emission for settings less than 5 minutes, to within 10 percent of the preset duration of emission for settings of from 5 minutes to 10 minutes, and to within 1 minute of the preset duration of emission for settings greater than 10 minutes.

(3) *Pulse duration and repetition rate.* A means shall be incorporated for indicating the magnitudes of pulse duration and pulse repetition rate of the emitted ultrasonic radiation, if there are operation controls for varying these quantities.

(4) *Ultrasonic frequency.* A means shall be incorporated for indicating the magnitude of the ultrasonic frequency of the emitted ultrasonic radiation, if there is an operation control for varying this quantity.

(5) *Visual indicator.* A means shall be incorporated to provide a clear, distinct, and readily understood visual indicator when and only when electrical energy of appropriate ultrasonic frequency is being applied to the ultrasonic transducer(s).

(d) *Labeling requirements.* In addition to the labeling requirements in Part 801 and the requirements of §§ 1010.2 and 1010.3 of this chapter, each ultrasonic therapy product shall be subject to the applicable labeling requirements of this paragraph.

(1) *Operation controls.* Each operation control shall be clearly labeled identifying the function controlled and, where appropriate, the units of measure of that function. If a separate control and indicator are associated with the same function, then labeling the appropriate units of measure of that function is required for the indicator but not for the control.

(2) *Service controls.* Each service control that is accessible without displacement or removal of any part of the ultrasonic therapy product shall be clearly labeled identifying the function controlled and shall include the phrase "for service adjustment only."

(3) *Generators.* (i) Each generator shall bear a label that states: The brand name, model designation, and unique serial number or other unique identification so that it is individually identifiable; ultrasonic frequency (unless there is an operation control for varying this quantity); and type of waveform (continuous wave or amplitude modulated).

(ii) Generators employing amplitude-modulated waveforms shall also bear a label that provides the following information: Pulse duration and pulse repetition rate (unless there are operation controls for varying these quantities), an illustration of the amplitude-modulated waveform, and the

ratio of the temporal-maximum effective intensity to the temporal-average effective intensity. (If this ratio is a function of any operation control setting, then the range of the ratio shall be specified, and the waveform illustration shall be provided for the maximum value of this ratio.)

(4) *Applicators.* Each applicator shall bear a label that provides the following information:

(i) The brand name, model designation, and unique serial number or other unique identification so the applicator is individually identifiable;

(ii) A designation of the generator(s) for which the applicator is intended; and

(iii) The ultrasonic frequency, effective radiating area, maximum beam nonuniformity ratio, type of applicator (focusing, collimating, diverging), and for a focusing applicator the focal length and focal area.

(5) *Label specifications.* Labels required by this paragraph shall be permanently affixed to or inscribed on the ultrasonic therapy product; they shall be legible and clearly visible. If the size, configuration, or design of the ultrasonic therapy product would preclude compliance with the requirements of this paragraph, the Director, Bureau of Radiological Health, may approve alternate means of providing such label(s).

(e) *Tests for determination of compliance*—(1) *Tests for certification.* Tests on which certification pursuant to § 1010.2 of this chapter is based shall account for all measurement errors and uncertainties. Such tests shall also account for increases in emission and degradation in radiation safety that occur with age.

(2) *Test conditions.* Except as provided in § 1010.13 of this chapter, tests for compliance with each of the applicable requirements of this section shall be made:

(i) For all possible combinations of adjustments of the controls listed in the operation instructions.

(ii) With the ultrasonic radiation emitted into the equivalent of an infinite medium of distilled, degassed water at 30° C for measurements concerning the ultrasonic radiation.

(iii) With line voltage variations in the range of ±10 percent of the rated value specified by the manufacturer.

(3) *Measurement parameters.* Measurements for determination of the spatial distribution of the ultrasonic radiation field shall be made with a detector having dimensions of less than one wavelength in water or an equivalent measurement technique.

(f) *Informational requirements*—(1) *Servicing information.* The manufacturer of an ultrasonic therapy product shall provide or cause to be provided to servicing dealers and distributors, and to others upon request, at a cost not to exceed the cost of preparation and distribution, adequate instructions for operation, service, and calibration, including a description of those controls and procedures that could be used to increase radiation emission levels, and a schedule of maintenance necessary to keep equipment in compliance with this section. The instructions shall include adequate safety precautions that may be necessary regarding ultrasonic radiation exposure.

(2) *User information.* The manufacturer of ultrasonic therapy product shall provide as an integral part of any user instruction or operation manual that is regularly supplied with the product, or, if not so supplied, shall cause to be provided with each ultrasonic therapy product, and to others upon request, at a cost not to exceed the cost of preparation and distribution:

(i) Adequate instructions concerning assembly, operation, safe use, any safety procedures and precautions that may be necessary regarding the use of ultrasonic radiation, and a schedule of maintenance necessary to keep the equipment in compliance with this section. The operation instructions shall include a discussion of all operation controls, and shall describe the effect of each control.

(ii) Adequate description of the spatial distribution of the ultrasonic radiation field and the orientation of the field with respect to the applicator. This will include a textual discussion with diagrams, plots, or photographs representative of the beam pattern. If there is more than one ultrasonic transducer in an applicator and their positions are not fixed relative to each other, then the description must specify the spatial distribution of the ultrasonic radiation field emitted by each ultrasonic transducer and present adequate examples of the combination field of the ultrasonic transducers with regard to safe use. The description of the ultrasonic radiation field shall state that such description applies under conditions specified in paragraph (e)(2)(ii) of this section.

(iii) Adequate description, as appropriate to the product, of the uncertainties in magnitude expressed in terms of percentage error, of the ultrasonic frequency, effective radiating area, and, where applicable, the ratio of the temporal-maximum effective intensity to the temporal-average effective intensity, pulse duration, pulse repetition rate, focal area, and focal length. The errors in indications specified in paragraphs (c)(1) and (c)(2) of this section shall be stated in the instruction manual.

(iv) A listing of controls, adjustments, and procedures for operation and maintenance, including the warning "Caution—use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous exposure to ultrasonic energy."

Effective date: This regulation shall become effective February 17, 1979.

(Sec. 358, 82 Stat. 1177-1179 (21 U.S.C. 263f).)

Dated: February 9, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

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